Supreme Court, U. S.
FILED
AUG 29 1980
MICHAEL RODAK, JR., CLERK

No. 80-23

In the Supreme Court of the United States

OCTOBER TERM, 1979

RICHARD SEELIG, TERRY HAWKINS AND DONALD PRIMMER, PETITIONERS

v.

UNITED STATES OF AMERICA

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SIXTH CIRCUIT

BRIEF FOR THE UNITED STATES IN OPPOSITION

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QUESTIONS PRESENTED

1. Whether petitioners were properly prosecuted under 21 U.S.C. 841(a)(1) for violating regulations promulgated by the Attorney General under the Controlled Substances Act, 21 U.S.C. 801 *et seq.*

2. Whether a government witness was improperly allowed to testify as to legal conclusions.

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OPINION BELOW

The opinion of the court of appeals (Pet. App. 19a-36a) is reported at 622 F. 2d 207.

JURISDICTION

The judgment of the court of appeals was entered on May 8, 1980. Mr. Justice Stewart extended the time for filing a petition for a writ of certiorari to and including July 7, 1980, and the petition was filed on that date. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATEMENT

Following a jury trial in the United States District Court for the Southern District of Ohio, petitioners, three registered pharmacists, were convicted on multiple misdemeanor counts of selling four-ounce bottles of cough medicine containing codeine (a schedule V controlled substance) to the same person within a 48-hour period, in violation of 21 U.S.C. 841(a)(1) and 21 C.F.R. 1306.32(b), and on multiple felony counts of refilling prescriptions for Valium and Darvon (schedule IV controlled substances) without physician authorization, in violation of 21 U.S.C. 841(a)(1) and 21 C.F.R. 1306.22(a) and 1306.23.[1] Petitioners Seelig and Hawkins were each sentenced to three-year terms of imprisonment, suspended in favor of three years' probation, and to fines totaling $10,000. Petitioner Primmer received the same sentences, except that his fines amounted to $5,000 (Pet. App. 43a-44a). On appeal, the court of appeals found the

[1]Petitioner Seelig was convicted on 19 misdemeanor counts and eight felony counts (Pet. App. 39a). Petitioner Hawkins was convicted on six misdemeanor counts and seven felony counts (*id.* at 41a). Petitioner Primmer was convicted on 18 misdemeanor counts and five felony counts (*id.* at 43a).

evidence sufficient to sustain petitioners' convictions, but it remanded for a new trial on the ground that the trial judge erred in admitting certain evidence and in giving certain instructions to the jury (Pet. App. 19a-36a).

The trial evidence showed that petitioners Seelig and Hawkins were co-owners of Seelig Pharmacies, Inc., which operated two retail drugstores in Columbus, Ohio. All three petitioners are registered pharmacists who worked in those stores. The pharmacies' record books for April and May 1978, which were obtained in connection with a DEA audit, showed "repeated occasions where more than four ounces of [codeine-based cough medicine] was sold to the same person within a 48 hour period" (Pet. App. 35a-36a). Five customers, including two undercover police officers, testified that they had made such purchases, including repeat purchases in the same store on the same day (II Tr. 25-37, 61-77, 88-105). Moreover, records of the pharmaceutical wholesalers serving the Selig stores showed that the stores had purchased unusually large amounts of codeine-based cough preparations (Gov. Exhs. 215-217).

Petitioners' records also showed that they had refilled or renewed Valium and Darvon prescriptions without authorization by the prescribing physician. While petitioners presented testimony to show that they routinely renewed prescriptions upon oral authorization (Pet. 7), several prescribing physicians testified that "their records failed to disclose oral authorizations for renewal of prescriptions and that it was their practice to record such oral authorizations" (Pet. App. 36a).

ARGUMENT

In *United States* v. *Grimaud*, 220 U.S. 506, 517-519 (1911), this Court held that a person may not be prosecuted for violating an administrative regulation

unless the underlying statute authorizes criminal prosecution for such a violation. The court below properly rejected petitioners' contention (Pet. 8-18) that the Controlled Substances Act provides no authority for criminal prosecutions based on violations of the regulations at issue here.[2] In an opinion upon which we rely in the main, the court of appeals held (Pet. App. 23a):

> The combination of [21 U.S.C.] §829(c) and §822(b)[3] thus requires a person to dispense or distribute a schedule V drug for a medical purpose and to be within the authority of their registration as determined by the Attorney General. Section 822(a) requires every person who distributes or dispenses controlled substances to register with the Attorney General. Section 821 authorizes the Attorney General to promulgate rules and regulations relating to the registration and control of the manufacture, distribution, and dispensing of controlled substances. Section 871(b) authorizes the

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[2]At the outset, we note that the petitioners are in essentially the same position as if the district court had denied a motion to dismiss this indictment. Petitioners have been granted a new trial and may be acquitted. If petitioners are convicted, they will be free to raise this issue at that time.

[3]Section 829(c) provides:

> No controlled substance in schedule V which is a drug may be distributed or dispensed other than for a medical purpose.

Section 822(b) provides:

> Persons registered by the Attorney General under this subchapter to manufacture, distribute, or dispense controlled substances are authorized to possess, manufacture, distribute, or dispense such substances (including any such activity in the conduct of research) to the extent authorized by their registration and in conformity with the other provisions of this subchapter.

> Attorney General to promulgate and enforce rules, regulations, and procedures that he deems necessary for the efficient execution of his functions.
>
> Although Congress was not as clear in this statute as in the one involved in *Grimaud*, this Court is satisfied that the statute does expressly, albeit in a convoluted fashion, provide that a violation of the promulgated rules constitutes an unlawful act under the Controlled Substances Act.[4]

The court also correctly observed (Pet. App. 23a-24a n.1), that

> [o]ther courts have had no problem finding defendants guilty under 21 U.S.C. §841(a)(1) for violating the regulations (primarily 21 C.F.R. §1306.04). See *United States* v. *Hayes*, 595 F. 2d 258, 259 (5th Cir.), *cert. denied*, 100 S. Ct. 138 (1979); *United States* v. *Roya*, 574 F. 2d 386, 390 (7th Cir.), *cert. denied*, 439 U.S. 857 (1978); *United States* v. *Pastor*, 557 F. 2d 930, 939 (2d Cir. 1977) *United States* v. *Rosenberg*, 515 F. 2d 190, 196-97 (9th Cir.), *cert. denied*, 423 U.S. 1031 (1975); *United States* v. *Green*, 511 F. 2d 1062, 1067-70 (7th Cir.), *cert. denied*, 423 U.S. 1031 (1975); *United States* v. *Larson*, 507 F. 2d 385, 386 (9th Cir. 1974); *United States* v. *Bartee*, 479 F. 2d 484, 488 (10th Cir. 1973).[5]

Petitioners attempt to avoid the weight of those decisions with the observation (Pet. 12) that those

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[4]Section 841(a)(1) provides in relevant part:

> (a) Except as authorized by this subchapter, it shall be unlawful for any person knowingly or intentionally—(1) to manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense, a controlled substance; * * *.

[5]Petitioners do not contend that the decision below conflicts with the decision of any other court of appeals.

prosecutions involved violations of 21 C.F.R. 1306.04, while this case involves violations of 21 C.F.R. 1302.22, 1306.23 and 1306.32. Petitioners assert that 21 C.F.R. 1306.04 presents a special case because it merely "mimics the statute" and does not "expand" the reach of the statute. That contention is ill-founded because 21 C.F.R. 1306.04 "mimics the statute" no more than do the regulations at issue here. Section 1306.04 provides that prescription drugs may not be dispensed except for a "legitimate medical purpose," a standard that the regulation also explains, and one that is not specifically set out in the statute. To be sure, the regulations here set more precise guidelines governing the dispensation of controlled drugs.[6] But, as the Seventh Circuit said in *United States* v. *Green*, 511 F. 2d 1062, 1070 (7th Cir.), cert. denied, 423 U.S. 1031 (1975), in upholding a conviction based on a violation of 21 C.F.R. 1306.04, "more precise regulations are desirable as to what physicians [or pharmacists] may or may not do" with respect to the dispensation of controlled drugs.

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[6]21 C.F.R. 1306.32(b) provides in relevant part that "[n]ot more than 24 dosage units [four ounces] of [codeine-based medicine] may be dispensed at retail to the same purchaser in any given 48-hour period."

21 C.F.R. 1306.22(a) provides in relevant part that "[n]o prescription for [schedule IV drugs] shall be filled or refilled more than 6 months after the date on which such prescription was issued and no such prescription authorized to be refilled may be refilled more than five times. * * * Additional [schedule IV drugs] may only be authorized by a prescribing practitioner through issuance of * * * a new and separate prescription."

21 C.F.R. 1306.23 provides in relevant part that partial filling of a prescription for a schedule IV drug is permissible providing "(a) [e]ach partial filling is recorded in the same manner as a refilling, (b) [t]he total quantity dispensed * * * does not exceed the total quantity prescribed, and (c) [n]o dispensing occurs after 6 months after the date on which the prescription was issued."

At all events, the statutory language and the legislative history support the authority of the Attorney General to promulgate regulations that "fill up the details" rather than simply "mimic the statute,"[7] and the power of Congress to confer that authority is equally clear. As the Court said in *Grimaud*, *supra*, 220 U.S. at 517:

> From the beginning of the Government various acts have been passed conferring upon executive officers power to make rules and regulations—not for the government of their departments, but for administering the laws which did govern. None of these statutes could confer legislative power. But when Congress had legislated and indicated its will, it could give to those who were to act under such general provisions "power to fill up the details" by the establishment of administrative rules and regulations, the violation of which could be punished by fine or imprisonment fixed by Congress, or by penalties fixed by Congress or measured by the injury done.

Moreover, the Attorney General's unquestioned authority to determine which drugs should be controlled[8] underscores his attendant authority to promulgate regulations, such as those at issue here, that merely set guidelines for the lawful dispensation of drugs that he has designated as controlled substances.

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[7]See H.R. Rep. No. 91-1444, 91st Cong., 2d Sess. 38, 51 (1970) (the statute "authorizes the Attorney General to promulgate rules and regulations * * * relating to the registration and control of the manufacture, distribution, and dispensing of substances covered by the act * * * and it authorizes him to promulgate rules and regulations for the efficient execution of his functions under title II [of the act].")

[8]See *United States* v. *Barron*, 594 F. 2d 1345, 1352-1353 (10th Cir.), cert. denied, 441 U.S. 951 (1979); *United States* v. *Dunbar*, 590 F. 2d

Nor is there any merit to petitioners' contention (Pet. 12-13) that 21 C.F.R. 1306.32 is arbitrary or "totally unrelated to the notion of 'medical purpose' " as that term is used in 21 U.S.C. 829(c). The regulation merely reflects the obvious fact that a person will rarely, if ever, have a legitimate medical need to consume more than one four-ounce bottle of codeine-based cough medicine within a two-day period.[9] Moreover, the trial evidence showed that a substantial amount of the cough medicine dispensed by petitioners was consumed not for medical purposes, but for purposes of getting "high" (II Tr. 25-26).[10]

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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AUGUST 1980

1340, 1342; *United States* v. *Roya*, 574 F. 2d 386, 392 (7th Cir. 1978); *United States* v. *Davis*, 564 F. 2d 840, 843-844 (9th Cir. 1977), cert. denied, 434 U.S. 1015 (1978); *United States* v. *Pastor*, *supra*, 557 F. 2d 930, 941 (2d Cir. 1977).

[9]FDA guidelines provide that the label on a four-ounce bottle of codeine-based cough medicine may not recommend a *maximum* adult dosage exceeding four ounces within a 48-hour period. See *Physicians Desk Reference* 1444 (34th ed. 1980).

[10]Petitioners' unrelated contention (Pet. 18-27) that the district court erred in allowing a DEA investigator "to testify as to his personal opinion of the Federal Law" was properly rejected by the court of appeals (Pet. App. 30a). In any event, that issue does not warrant review because it relates to the specific content of a witness's trial testimony, and petitioners have now been granted a new trial.